

Grant Final Report

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**Symptom Monitoring and Reporting System for
Chronic Illness Pediatric Populations**

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Principal Investigator:

Jin-Shei Lai, PhD, OTR/L

Team Members:

Susan Yount, PhD

Stewart Goldman, MD

Jennifer Beaumont, MS

Performing Organization:

Medical Social Sciences, Northwestern University

Project Officer:

Iris R. Mabry-Hernandez

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The Agency for Healthcare Research and Quality (AHRQ)

U.S. Department of Health and Human Services

540 Gaither Road

Rockville, MD 20850

www.ahrq.gov

Structured Abstract

Purpose: This study evaluated the feasibility of implementing SyMon-SAYS in pediatric oncology clinics using fatigue as a prototype symptom.

Scope: Timely identification of symptoms related to multi-modal therapy for children with cancer is fundamental to the overall success of cancer treatment. SyMon-SAYS, a patient-oriented, technology-based symptom monitoring and reporting system, was developed to fill this need.

Methods: Patients with a cancer diagnosis, ages 7-21 years, on- or off-treatment within 6 months, were eligible. Patients/parents completed weekly fatigue assessments over eight weeks via the internet or interactive voice response (IVR) by phone. Alert emails were generated when pre-defined fatigue score thresholds were met, and fatigue reports were forwarded to clinicians accordingly. Clinicians and parents/patients received cumulative graphic reports of fatigue scores prior to clinic visits at 4 and 8 weeks post-baseline to facilitate discussion. Parents/patients completed an exit survey at their last visit.

Results: Fifty-seven patients/parents completed the study. The majority of patients (93%) and parents (78%) felt it was very/extremely easy to complete SyMon-SAYS, 95% of parents were satisfied with SyMon-SAYS, 60% reported SyMon-SAYS helped deal with their child's fatigue, 70% reported that clinicians did not discuss fatigue with them, and 81% were willing to use SyMon-SAYS to manage fatigue and other symptoms. Clinicians reported insufficient time to review reports, yet 64% were willing to receive the report on a monthly basis. Results suggest SyMon-SAYS is feasible and acceptable to patients and parents. Future efforts should focus on better integrating SyMon-SAYS into the clinical workflow to improve clinicians' acceptance.

Key Words: symptom monitoring; symptoms; children; oncology; fatigue

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Final Report

Purpose

The overall objective of the proposed work was to build and test the Symptom Monitoring & Systematic Assessment in Young Survivors (SyMon-SAYS), formerly “Monitoring and Reporting System in Pediatric populations (SyMon-Peds)”, using oncology as a starting point. We believe SyMon-SAYS can facilitate productive interactions between patients, family members and health care providers as described in Wagner’s model for improvement of chronic illness care.^{1,2} By alerting patients and providers to significant changes in symptom severity, the SyMon system facilitates patient-centered, coordinated clinical care and patient self-management. However, such a symptom monitoring system has not been tested in pediatric populations. Given the exploratory nature of the proposed study, we focused only on a single symptom, fatigue, because it is a nearly universal experience for cancer patients of all ages across the disease and treatment continua.³⁻¹⁰

Objectives of the study

- Evaluate the feasibility of implementing the SyMon-SAYS system in a pediatric oncology clinic, its acceptability by parents of children with cancer and the clinicians’ and parents’ satisfaction with the system.
- Explore the efficacy of the SyMon-Peds in managing fatigue.

Scope

Background

Efforts to manage cancer-related symptoms in children have not kept pace with advances in cancer treatments. Children continue to experience distressing physical symptoms caused by cancer and its treatment.¹¹⁻¹³ Cancer can be distressing in part due to the unrelieved symptoms caused by aggressive therapy regimens implemented to treat the disease.¹³ Factors contributing to poor symptom management exist at the patient, health care provider and system levels. Health care system barriers are related to the structure of care, reimbursement and resources,¹⁴ logistics and organizational barriers that limit the quality of symptom care for patients with cancer.¹⁵ Health care provider barriers include limitations on time available during a typical patient encounter,¹⁶ staff ability and willingness to elicit relevant information from patients,^{15,17,18} infrequent use of systematic symptom assessment,^{19,20} and particularly in pediatrics, clinician uncertainty about the accuracy of patient reports. Most of the literature addressing patient barriers is based on adult populations and includes barriers such as forgetfulness,²¹ concern that

complaints may be perceived as criticism of physicians' clinical skills,¹⁵ or desire to be a "good patient".^{15,22-24}

The literature suggests that symptom management programs in adult cancer patients are feasible, may improve care, enhance patient and provider satisfaction, and lessen symptom burden, while being unlikely to increase provider time and effort. The programs may also increase self-management, which is a desirable goal for children and adolescents who have significant ongoing health care needs related to a chronic illness. Such programs have been developed and tested in adult populations but not in children with cancer, where this is a significant need. In this study, we developed an automatic routine symptom monitoring and reporting program, SyMon-SAYS, to hopefully fill this void.

Context

The conceptual framework on which SyMon-SAYS is based is Wagner's model for improvement of chronic illness care.^{1,2,25} The model emphasizes healthcare processes that meet the needs of patients and their parents in managing chronic illness. Wagner proposes that improvement in chronic illness outcomes are maximized when clinical systems reconfigure themselves to include, among other things, structured interactions with patients and their parents, continual follow-up by healthcare providers, a focus on function and prevention of symptom exacerbations, systematic assessments, adherence to evidence-based treatment guidelines, behaviorally-minded self-management support for patients and their parents, and information systems that can facilitate tracking symptoms and clinical reminders. By assessing patients' symptoms between clinic visits using a computer-based telephone/internet monitoring and reporting technology, the SyMon-SAYS system provides results of systematic assessments to both providers and patients and their parents with the ultimate goal of improving symptom management by promoting productive interactions between informed, activated patients and parents and the prepared, proactive clinical practice team.

SyMon-SAYS is a clinically relevant assessment and information system intended to track patients' symptoms and alert clinicians to symptoms in real-time so that problems can be targeted proactively and subsequent follow-up care can be structured around minimizing symptoms and improving functioning. Because the SyMon-SAYS system can help patients and parents better track symptoms, it aims to improve not only clinical care and patient/parent-provider interactions but also patient/parent self-management. The symptom monitoring and reporting capabilities allow patients/parents and providers to participate in "same goal-coordinated care," which is achieved via productive communications that focus on areas of concerns and care strategies. This improved communication may then enhance patients'/parents' abilities to self-manage symptoms and enhance their ability to follow treatment, medication, and monitoring regimens. Through improved control of symptoms there may be increased functionality and quality of life.

Setting

Patients and their parents completed the study in pediatric oncology clinics in Ann and Robert H. Lurie's Children's Hospital of Chicago and their home.

Participants

Eligible patient and parent dyads were recruited from oncology clinics in the Ann and Robert H. Lurie Children's Hospital of Chicago, formerly Children's Memorial Hospital, Chicago. The inclusion criteria were: 1) a cancer diagnosis, 2) between 7 and 21 years old, 3) receiving any type of treatment or having completed it within the previous 6 months, 4) English-speaking, and 5) having sufficient cognitive and motor abilities to operate the telephone keypad or computer keyboard or mouse. Parents of eligible patients were eligible for the study if they demonstrated sufficient English ability to understand and sign the informed consent form, complete assessments at all time-points, and had sufficient cognitive and motor abilities to operate the telephone keypad or computer keyboard or mouse.

Methods

Study Design

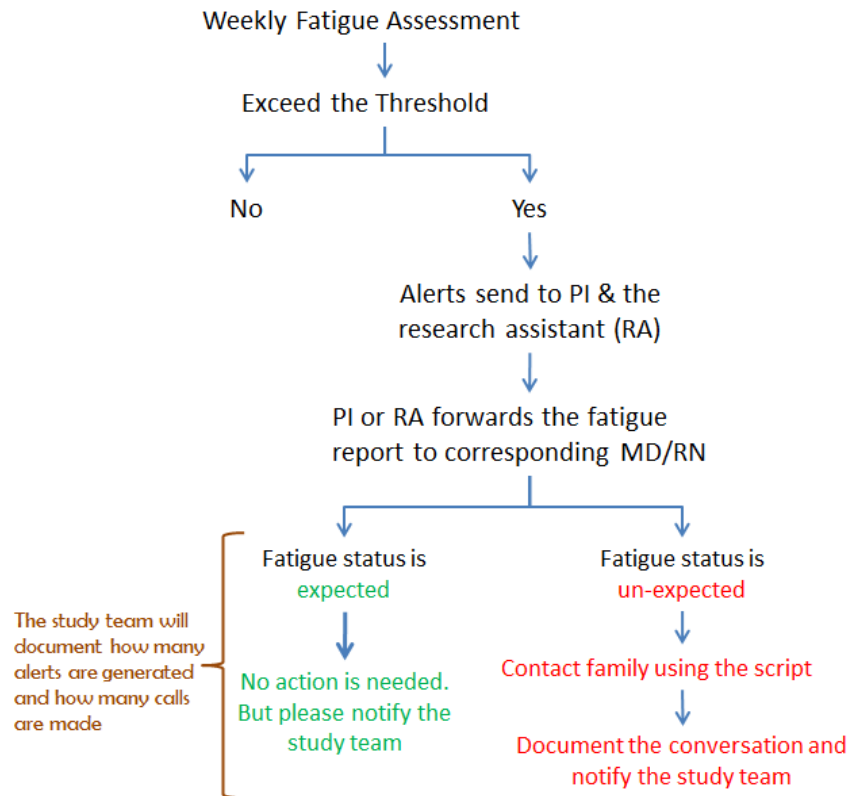
The SyMon-SAYS system consists of *participant* and *clinician* interfaces that collectively allow for the collection, storage and supervision of data, generating reports, and for the overall organization and administration of the proposed project. SyMon-SAYS is accessible via any device with internet access and telephone via Interactive Voice Response (i.e., IVR). Participant data is stored in a structured format of one item per response per person, allowing almost unlimited flexibility for analysis. The software maintains a relational database using Structural Query Language (SQL) to record and manage all study data. Data collected from all modes are automatically stored in a single database.

The participant (i.e., both patient and parent) interface is a self-survey system used to gather symptom information from participants through various modes of administration. The clinician interface is for use by clinicians and study personnel. It includes modules for participant registration, reporting, and data management. For this study, the SyMon-SAYS system generated fatigue symptom reports based on data collected from participants. Individual fatigue symptom reports were provided to clinicians at the week-4 and week-8 visits, detailing in graphic display weekly symptom reports and highlighting changes from week to week. The study schema is shown on Figure 1.

Data Sources/Collection

After enrollment, participants completed the questionnaires as listed in the Measures Section: at baseline, week-4 and week-8 in clinic. They were also trained on accessing SyMon-SAYS system and were provided with a card containing their unique ID code as well as brief instructions for using the system. Participants were asked to choose a standard day of the week to access the system and complete the fatigue assessment. The research assistant (RA) instructed participants on how to access the SyMon-SAYS system. Participants were asked to complete the pedsFACIT-Fatigue on a weekly basis for 8 weeks either by telephone (i.e., IVR) or internet depending on their preference. If participants did not access the system by midnight of the

Figure 1. SyMon-SAYS weekly assessment flowchart



preferred day, the RA contacted the parents the following business day and reminded them or their children to complete the assessment. If the participant did not access the system by midnight of the day following their preferred day, the RA again attempted to contact the parents by phone to either remind them or their children to access the system. Both patients and parents were also asked to complete an exit survey to evaluate the feasibility and acceptability of the SyMon-SAYS system.

Participating clinicians were asked to complete evaluations of the SyMon-SAYS system monthly. This evaluation form obtained clinicians' perceptions of the usefulness and acceptability of the SyMon-SAYS system, the extent to which the symptom reports were helpful in discussions with patients/parents, how helpful the reports were in managing patients' care, the degree to which the system and reports affected communication or treatment decision-making with patients/parents, and whether or not physicians/nurses would be receptive to using such a system if it was available on an on-going basis.

Intervention: Report and E-mail Alert when Fatigue Threshold was met

Fatigue scores reported by patients on a weekly basis for 8 weeks either via telephone or internet were stored in the database as described in the SyMon-SAYS system architecture (C.1). Graphic and text-based feedback were generated immediately prior to the week-4 and week-8

visits and provided for review by parents and clinicians. The intervention trigger in our study was either a reported pedsFACIT-Fatigue score that was one SD worse than the general population-based norm or the fatigue change score 1 SD worse than was reported in the prior week. As demonstrated in Figure 1, fatigue scores reported by patients were monitored and reported to their oncology care providers. When the fatigue score trigger was met, the system generated an email alert sent to the study team, and the study team forwarded the report, which documented all available weekly fatigue scores, to the treating MD and RN. Clinicians decided whether contacting parents was necessary.

Study staff printed out reports and delivered them to physicians and parents at Weeks 4 and 8 during their clinic visits regardless their fatigue scores. These reports reflected patients' cumulative fatigue scores between baseline and Week 4 and between Week 4 to Week 8 from both patients' and parents' perspectives. Parents were encouraged to discuss the symptom reports with their children's physicians.

Measures

Participants completed the following questionnaires at baseline, week-4 and week-8 in clinic: Pediatric Functional Assessment of Chronic Illness-General and Functional Assessment of Chronic Illness - Fatigue³ (pedsFACIT-F) (patients and parents), The National Comprehensive Cancer Network (NCCN) 0-10 fatigue rating (patients and parents),²⁶ Fatigue Management Barriers Questionnaire¹⁷ (FMBQ) (parents only), Symptom (Fatigue) Distress Scale (SDS) (patients and parents), Health-Protective Behavior²⁷ (HPB) (patients and parents), and Neuro-QOL Pediatric short-forms. Patients and parents also completed pedsFACIT-F every week for 8 weeks.

Limitation

Many participants required reminders to complete the weekly assessments. Yet, making reminder calls was labor intensive. More cost-effective designs should be tested in future studies to improve adherence of participants completing the weekly assessments (e.g., automated reminder messages).

Results

Principal Findings

Sample. Sixty-three dyads were recruited and completed the baseline assessments; 6 of them (9.5%) later withdrew from this study. As a result, 57 patients (children), receiving or having completed treatment within 6 months completed the study. That sample of patients had mean age=11.9 years (SD=3.6); 46.4% were females; and 72% were white. In terms of clinical characteristics, 41.3% were diagnosed with brain tumors and 38.1% were diagnosed with leukemia. Most (98%) patients received chemotherapy, 46.8% received radiation therapy, and

42% received cancer-related surgery. Parents reported their child had significantly worse fatigue than patients' own reports, as measured by using a 0-10 fatigue rating, mean=2.67 (SD=2.12) and 3.68 (SD=2.25) for patients and parents, respectively ($t=-3.95$ $p=0.0003$). Sample characteristics are shown in Table 1 (patient) and Table 2 (parent). Symptoms reported by patients and parents are shown in Table 3. There were no significant differences in symptoms reported by patients and parents at $p=0.05$ level. Moderate agreement (weighted Kappa ranged from 0.16 to 0.51) was noted between these two groups.

Table 1. Sample characteristics (Patients; N=62)

Variable	Value	Percentage
Gender	Male	53.6
Gender	Female	46.4
Hispanic Origin	Yes	25.0
Race	White	72.2
Race	African-American	9.3
Race	Asian	1.9
Race	Other race/multiple races	16.7
Quality of life rated by parents	Fair	8.9
Quality of life rated by parents	Good	37.5
Quality of life rated by parents	Very good	37.5
Quality of life rated by parents	Excellent	16.1
Type of cancer	Brain/spinal cord tumor	41.3
Type of cancer	Leukemia	38.1
Type of cancer	Non-Hodgkin's lymphoma	6.4
Type of cancer	Ewing's sarcoma	4.8
Type of cancer	Hodgkin's disease	3.2
Type of cancer	Rhabdomyosarcoma	1.6
Type of cancer	Other cancer	4.8
Extent of disease	Local	35.0
Extent of disease	Regional	6.7
Extent of disease	Metastasis	6.7
Extent of disease	NED	3.3
Extent of disease	NA	48.3
Treatment	Chemotherapy	98.4
Treatment	Radiation	46.8
Treatment	Surgery	42.6
Karnofsky	70	1.8
Karnofsky	80	10.9
Karnofsky	90	30.9
Karnofsky	100	56.4

Table 1a. Child characteristics

Variable	Mean, SD
Child age	mean=11.9 (SD=3.6)
Days missing school in the past month	mean=7.8 (SD=8.8; range: 0-30)
Hemoglobin(mg/l)	mean=12.0 (SD=1.7; range: 8-15)

Table 2. Parent characteristics (N=62)

Variable	Value	Percentage
Gender (Relationship with child)	Male (Father)	23.2
Gender (Relationship with child)	Female (Mother)	76.8
Spanish/Hispanic/Latino origin	No	78.6
Spanish/Hispanic/Latino origin	Yes	21.4
Race	White	74.6
Race	African-American	7.3
Race	Asian	3.6
Race	Other race/multiple races	12.7
Marital status	Married	81.8
Marital status	Living with partner in committed relationship	7.3
Marital status	Separated	1.8
Marital status	Divorced	9.1
Highest education	High school graduate or lower	23.2
Highest education	Some college	16.1
Highest education	College degree	42.9
Highest education	Advanced degree	17.9
Occupation status	Full-time employed	50.0
Occupation status	Homemaker	26.8
Occupation status	Unemployed	8.9
Occupation status	On leave of absence	7.1
Occupation status	Part-time employed	7.1

* "Parent" referred to either mother or father who completed information at the baseline

Table 3. Symptom Distress Scale (SDS) Scores of Patients (N=62) and Parents (N=52) at Baseline

Symptom	Value	Patient Report (%)	Parent Report (%)	p (t-test)	Weighted Kappa
Getting Around	Able to do everything	54.24	58.93	0.10	0.16
Getting Around	2	22.03	30.36		
Getting Around	3	13.56	7.14		
Getting Around	4	8.47	1.79		
Getting Around	Not able to get around at all	1.69	1.79		
Tired	Not tired at all	25.00	35.71	0.20	0.35
Tired	2	40.00	35.71		

Symptom	Value	Patient Report (%)	Parent Report (%)	p (t-test)	Weighted Kappa
Tired	3	21.67	25.00		
Tired	4	13.33	1.79		
Tired	Could not feel more tired	0	1.79		
Feeling	Could not feel happier	33.87	29.09	0.57	0.36
Feeling	2	35.48	34.55		
Feeling	3	24.19	34.55		
Feeling	4	6.45	0		
Feeling	Could not feel miserable	0	1.82		
Sleep	A perfect night	43.55	33.93	0.23	0.25
Sleep	2	24.19	50.00		
Sleep	3	17.74	14.29		
Sleep	4	6.45	1.79		
Sleep	Couldn't have been worse	8.06	0		
Appetite	Normal appetite	51.61	60.71	0.88	0.51
Appetite	2	25.81	8.93		
Appetite	3	12.9	17.86		
Appetite	4	6.45	10.71		
Appetite	Cannot face food at all	3.23	1.79		
Concentration	Normal concentration	52.46	69.09	0.10	0.21
Concentration	2	22.95	20.00		
Concentration	3	21.31	9.09		
Concentration	4	3.28	0		
Concentration	Cannot concentrate at all	0	1.82		

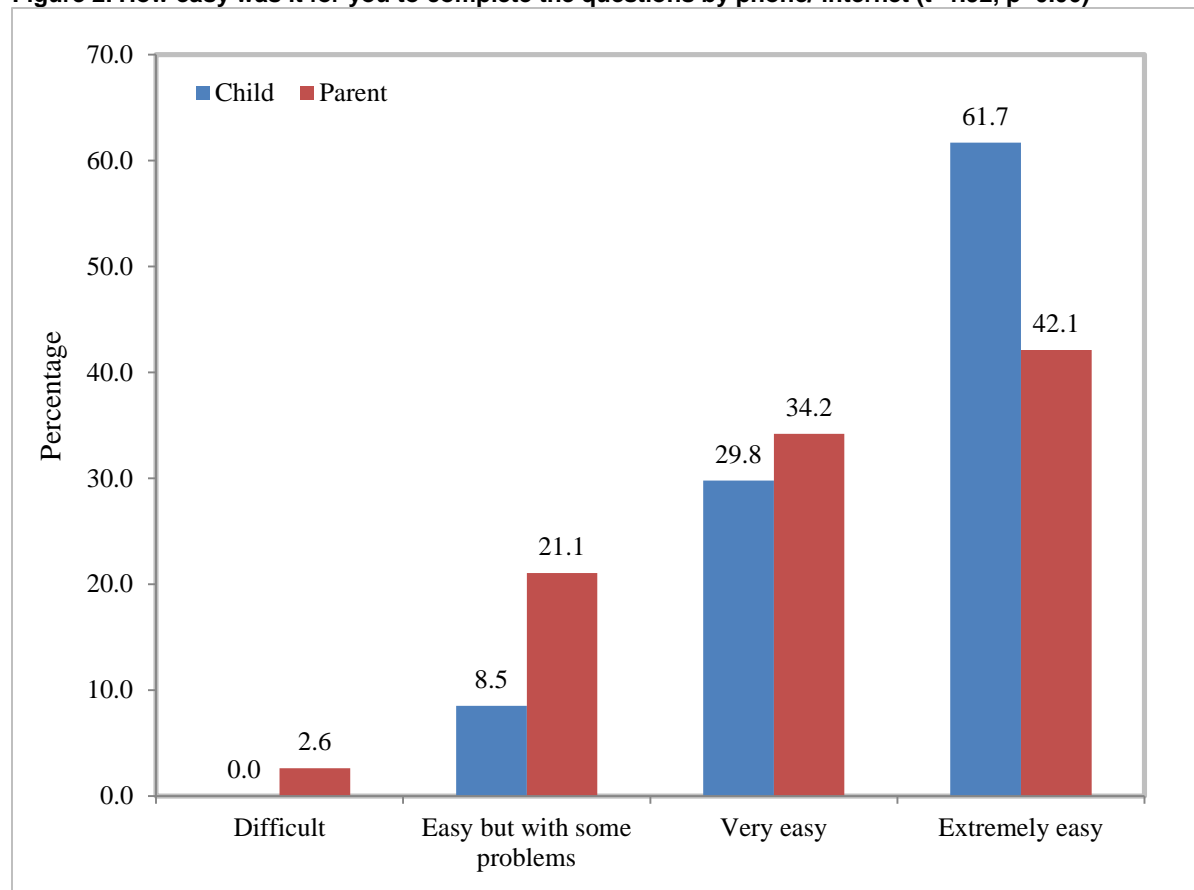
Adherence. Fifty-five reminder calls were made by the study team to complete the weekly assessment. An average of 6.1 (SD=2.6) assessments were completed by each participant (maximum possible number of assessments = 9). Parents had slightly better compliance than patients as indicated by the number of completed assessments: 5.96 (SD= 2.64) and 6.34 (SD=2.65) for patients and parents, respectively. A total of 54 alerts were generated during the study period informing the clinical team that a patient's fatigue level reached the predefined threshold.

Acceptability of SyMon-SAYS and efficacy of using SyMon-SAYS in managing fatigue.

Patients. A majority of patients (85%) did not have any problems using the telephone or internet to access SyMon-SAYS and felt it was extremely (62%) or very easy (30%) to complete the survey (see Figure 2). Only 51% of patients said their parents showed them the graph produced by the SyMon-SAYS system. About 39% of patients were willing to complete the SyMon-SAYS survey "as needed", 26% "weekly", 22% "every doctor's appointment" or 13% "monthly" (see Figure 3); and 81% preferred to complete the survey by internet versus 19% by telephone (i.e., IVR).

Parents. A majority (75%) of parents did not report any problems using SyMon-SAYS, felt it was extremely (42%) or very easy (34%) to complete the questions by phone (see Figure 2). Compared to the responses from patients, there was a trend for parents to report more difficulty in completing the SyMon-SAYS, $t=1.92$ $p=0.063$. Overall, parents were either very satisfied (49%) or satisfied (46%) with the SyMon-SAYS program. Most (71%) of them were willing to use SyMon-SAYS as part of their child's care, and 76% were willing to use it if other symptoms

Figure 2. How easy was it for you to complete the questions by phone/ internet ($t=1.92$, $p=0.06$)

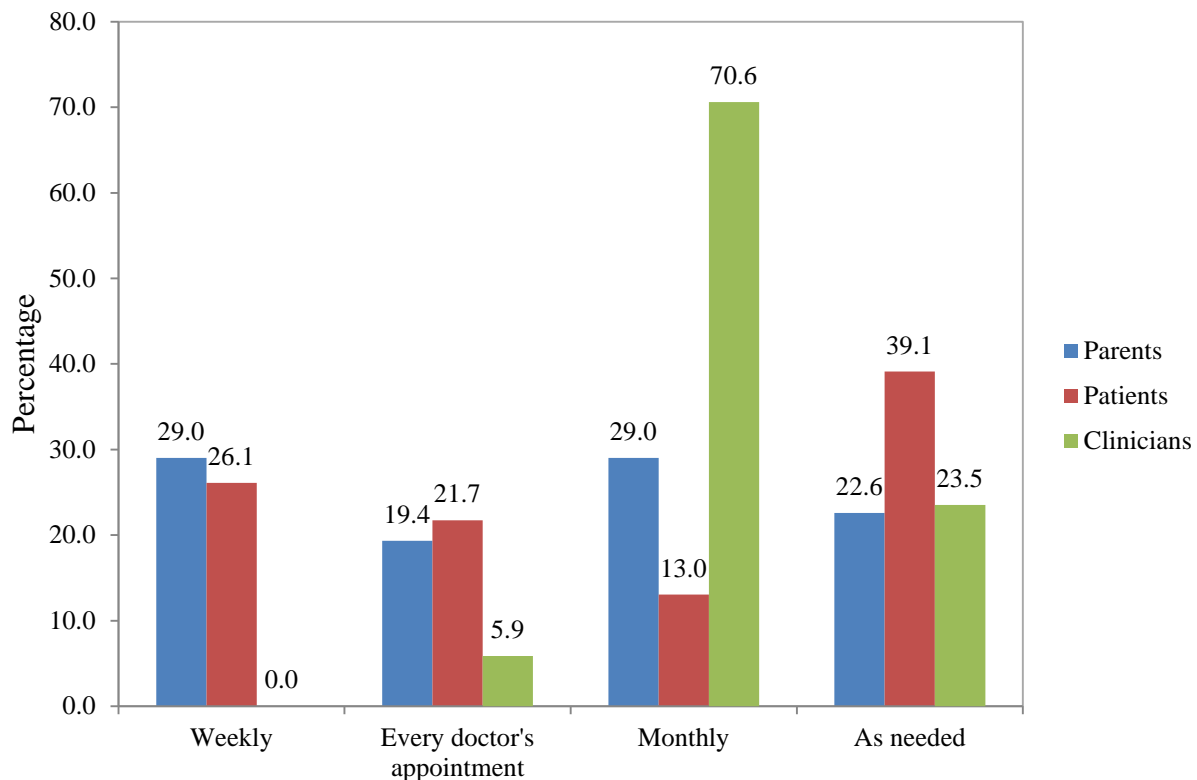


were also included in the SyMon-SAYS system. The preferred time to complete the SyMon-SAYS survey varied, with 29% preferring weekly, 29% monthly, 23% as needed and 19% at every doctor's visit (see Figure 3); this was not significantly different from children's responses ($t=1.52$, $p=0.14$). Seventy percent felt the internet was more convenient than the telephone, and 74% preferred to use the internet (versus 26% the telephone, i.e., IVR) when completing the questions.

About 58% of parents reported that SyMon-SAYS helped them deal more effectively with their child's fatigue. However, many parents felt that their participation in this study did not help their doctors or nurses treat their child's fatigue (35% "not at all"; 19% "a little bit"; 22% "somewhat"; 8% "quite a bit"; 16% "very much").

Inconsistent feedback about the fatigue report was found. Specifically, 58% of parents reported the fatigue report was at least somewhat helpful in understanding their child’s fatigue; 49% felt the report was helpful in discussing with doctors regarding the fatigue treatment; and 62% felt it was helpful to have a report to take home. However, only 35% of parents felt the weekly survey and reports helped them talk to their doctors or nurses. We also found that 71% of parents reported that their doctors or nurses did not discuss the SyMon-SAYS fatigue results with them (47% “never”, 24% “seldom”). We hypothesized that clinicians’ perceptions of limited clinical utility of the report may have contributed to clinicians’ decision not to discuss the report with parents.

Figure 3. Frequency of willingness to use SyMon-SAYS



- Question to patients and parents: How often would you be willing to answer the questions by telephone or internet?
- Question to clinicians: how often would you like your patient to complete fatigue assessments?

Clinicians. Twenty four evaluations from 13 clinicians were received. Of these 24 evaluations, 17 (69%) reported their participation in this study did not add to their workload (12%) or did so “a little bit” (58%). However, only 36% said that SyMon-SAYS had an impact on their fatigue management. Sixty percent of the clinicians’ evaluations indicated that SyMon-SAYS would be helpful in the overall care for their patients, and 68% stated that most children with cancer would benefit from SyMon-SAYS. Finally, 67% reported that they would be willing to use SyMon-SAYS as an on-going basis, and 75% would be willing to use it if more symptoms are included. Clinicians reported insufficient time to review reports. Yet, a majority (71%) was willing to receive the report on a monthly basis, 24% as needed and 6% on every visit (see

Figure 3). Clinicians' perceptions about the fatigue report produced by SyMon-SAYS are summarized in Figure 4. In brief, clinicians felt the report was understandable, useful for fatigue management and did not make the visit longer than usual. There were diverse opinions about whether the report guided focused discussion about their child's fatigue or indicated additional issues to address with patients. However, a majority did not think the report helped them to prepare to see patients, with treatment planning or decision making, or to focus on the most important issues to discuss with patients/parents.

Efficacy. The change from baseline in outcome scores is summarized in Table 4. In general, Week 4 scores were unchanged compared to baseline with the exception of self-reported Anxiety, which improved by 2.31 points ($p=0.046$). At Week 8 (or Exit assessment), there were statistically significant improvements in self-reported pain (3.12 points, $p=0.009$) and depression (2.21 points, $p=0.046$) and parent-reported stigma to patients (2.69 points, $p=0.004$) and patients' fatigue (1.00 points, $p=0.012$).

Figure 4. Clinicians' perceptions of the fatigue report produced by the SyMon-SAYS (N= 24)

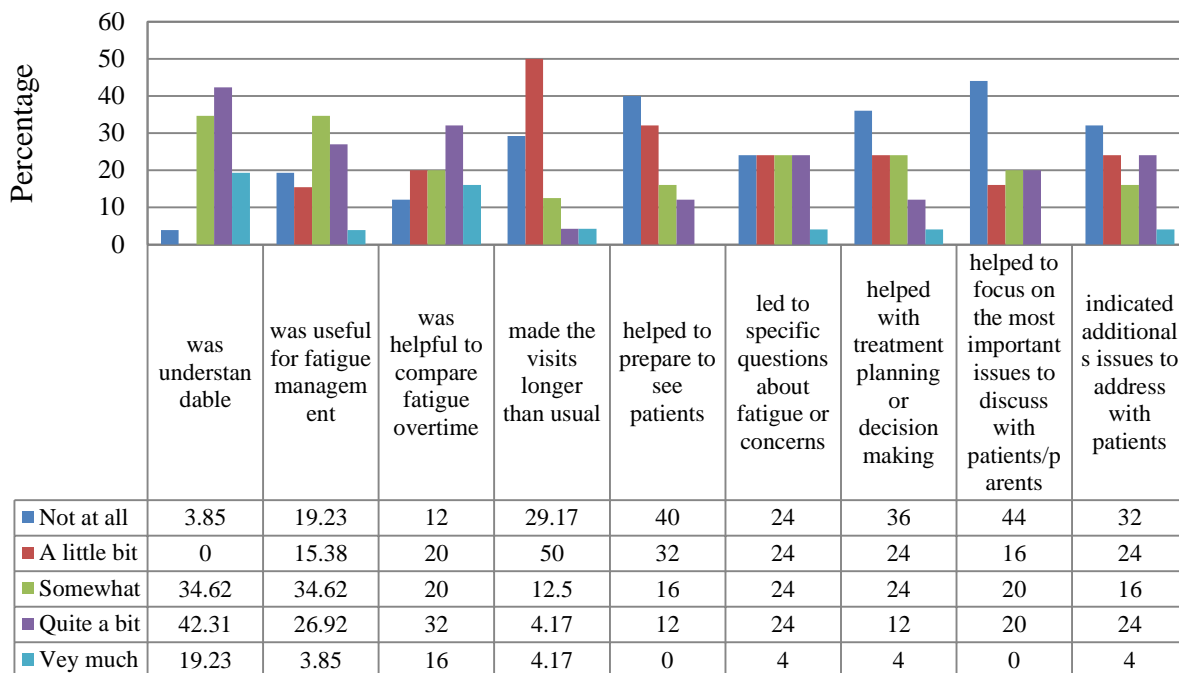


Table 4. Change from baseline in outcome scores reported by patients and parents

		Week 4 vs, Baseline			Week 8 (exit**) vs. Baseline		
	Variable	n	Mean change (SD)	p	n	Mean change (SD)	p
Child	Symptom Distress Score (6-30)	41	0.54 (4.91)	0.488	48	-0.79 (4.47)	0.226
Parent	Symptom Distress Score (6-30)	36	0.64 (4.57)	0.407	39	-0.72 (4.06)	0.276
Child	Fatigue rating (0-10)	41	0.59 (2.68)	0.170	47	0.57 (2.64)	0.143
Parent	Fatigue rating (0-10)*	36	-0.61 (2.44)	0.142	39	-1.00 (2.36)	0.012
Child	Neuro-QOL Stigma T-Score	37	-1.58 (5.86)	0.109	46	-0.64 (6.35)	0.498

Parent	Neuro-QOL Stigma T-Score*	32	-0.80 (4.56)	0.329	36	-2.69 (5.21)	0.004
Child	Neuro-QOL Depression T-Score*	35	-0.54 (6.13)	0.604	42	-2.21 (6.94)	0.046
Parent	Neuro-QOL Depression T-Score	33	-0.71 (7.15)	0.574	37	-1.13 (6.33)	0.285
Child	Neuro-QOL Anxiety T-Score*	39	-2.31 (6.99)	0.046	44	-1.30 (7.38)	0.249
Parent	Neuro-QOL Anxiety T-Score	28	-0.97 (6.21)	0.415	35	-0.05 (5.35)	0.960
Child	Neuro-QOL SR Interaction w Peers T-Score	40	0.31 (7.43)	0.792	45	1.22 (8.13)	0.318
Parent	Neuro-QOL SR Interaction w Peers T-Score	34	-1.19 (6.40)	0.286	38	0.90 (6.63)	0.408
Child	Neuro-QOL Pain T-Score*	36	-1.73 (5.76)	0.080	41	-3.12 (7.27)	0.009
Parent	Neuro-QOL Pain T-Score	24	-0.97 (6.03)	0.439	26	-1.00 (4.04)	0.220
Child	Peds FACIT-General – Physical	40	1.16 (3.88)	0.067	48	0.58 (4.26)	0.348
Parent	Peds FACIT-General – Physical	35	-0.72 (3.67)	0.252	38	-0.09 (3.68)	0.878
Child	Peds FACIT-General – Emotional	39	0.89 (5.78)	0.344	48	1.30 (5.89)	0.132
Parent	Peds FACIT-General – Emotional	36	-0.09 (4.10)	0.891	39	0.30 (6.62)	0.780
Child	Peds FACIT-General – Social	39	0.44 (2.51)	0.285	48	0.32 (2.68)	0.416
Parent	Peds FACIT-General – Social	36	0.03 (2.25)	0.927	39	0.10 (2.44)	0.794
Child	Peds FACIT-General – Total	39	2.51 (9.39)	0.104	48	2.21 (10.23)	0.142
Parent	Peds FACIT-General – Total	35	-0.76 (8.29)	0.590	38	0.52 (10.01)	0.748
Parent	FMBQ – Treatment futility	36	-0.36 (2.74)	0.424	39	0.21 (2.21)	0.566
Parent	FMBQ – Fear of disease progression	36	0.03 (1.50)	0.912	39	0.05 (1.28)	0.803
Parent	FMBQ – Fear of distracting doctor	36	-0.11 (1.70)	0.698	39	0.28 (1.47)	0.238
Parent	FMBQ – Lack of concern	36	-0.22 (2.93)	0.652	39	-0.85 (2.78)	0.065
Parent	FMBQ – Fear of stigma	36	-0.19 (1.74)	0.506	39	0.21 (1.79)	0.480
Parent	FMBQ – General medication concerns	36	-0.19 (3.12)	0.710	39	-0.26 (2.94)	0.590
Parent	FMBQ – Preference of non-medication interventions	36	-0.11 (1.83)	0.718	39	-0.26 (1.68)	0.347
Parent	FMBQ – Fear of jeopardizing cancer treatment	36	-0.25 (1.27)	0.247	39	-0.21 (1.30)	0.331
Parent	FMBQ – Lack of communication	36	0.33 (1.77)	0.267	39	0.13 (1.54)	0.607

* p<0.05

** Participants were asked to complete exit survey regardless how many weekly fatigue assessments they completed so some might skip week-4 assessment but still had exit data available.

Potential Influential Factors. The number of assessments completed was not significantly correlated with the fatigue rating (0-10 rating) at baseline ($r=0.20$, $p=0.14$ and $r=0.09$, $p=0.53$ for child and parent, respectively); was not significantly different between patients with brain tumors versus non-brain tumors ($t=0.43$, $p=0.67$); and did not differ by parents' marital status (married versus non-married; $t=-0.79$ $p=0.43$) or employment status (full-time employed versus non full-time employed; $t=-1.15$ $p=0.26$). It was also not correlated with symptom distress as measured by the Symptom Distress Scale, reported by both parents and patients ($r<0.3$ and $p>0.05$ for all symptoms). It was also not related to whether physicians discussed the report with parents/patients ($t=-0.02$ $p=0.98$).

Interviews with clinicians. Six clinicians (3 neuro-oncology nurses, 1 general oncology nurse and 2 neuro-oncologist physicians) were interviewed to further understand the barriers contributing to recruitment difficulties.

If a patient's fatigue report met a certain threshold, it generated an email "alert." Five of 6 clinicians contacted families if the fatigue scores changed unexpectedly. One clinician contacted families at the outset, but because she felt she was unable to provide an effective fatigue intervention, she decided not to continue to call families. None of the 5 clinicians reported having difficulties talking to families. Two clinicians reported that some families appreciated their calls. For example,

"...Actually some families liked me calling them and it was also nice to know how patients are doing. There was an example of a kid who had a cold-like symptom. The family was surprised that this symptom was reflected on the kid's fatigue score as the kid did not elaborate his feeling to parents. The parents were surprised I was contacting them regarding the kid's fatigue score but very much appreciated the call because otherwise they would have not known..."

All interviewees felt the alert trigger thresholds (i.e., 1 SD worse than the norm or 1 SD worse than the prior fatigue score) were appropriate; yet some also stated that change scores were more useful than comparisons to the norm. For example,

"...I would like to receive alerts when "change scores" exceed a threshold, not the actual scores. We saw patients at baseline and knew the fatigue the patient experienced, so there is no need to get an alert regarding the actual scores."

Four of 6 interviewees felt the report was informative. They would be more motivated to use the SyMon-SAYS if other symptoms were included in the report in the future.

"...The alerts usually matched kids' clinical conditions. Even though fatigue is expected, I still want to receive alerts in order to understand how kids are doing. For example, we knew kids were likely to have anemia. Receiving the alert let us know whether this kid does have this issue and we could go ahead to implement interventions such as blood transfusion so that kids do not need to suffer extra days ... Another example, I received an alert which was unexpected and found out that the kid's tumor progressed. We were able to deal with this situation more efficiently."

"...Unfortunately, these were not helpful to me only because the patients who I was alerted about had expected fatigue. If I was alerted on a unexpected patient it would have been more helpful, but this was my current experience."

"...Kids were alerted about fatigue, they were expected. Off-treatment might be better but the on-treatment does not really help."

Though interviewees felt the report could be useful, all clinicians reported they did not have sufficient time to review reports prior to seeing patients and would have preferred to have received reports one day prior to patients' clinical visits.

“...There should be a better way to streamline the process with a consistent manner. Clinics are always crazy and I sometimes do not know whether I should receive a report or not. It would be good to have some indication that this patient is enrolled in the study and I should expect to receive a report today. There should be a good and mutual understanding about patients’ enrollment status.”

“...Report is very useful. I knew what I was going to talk to patients about their fatigue with this report in hand. I sometimes forgot about asking patients about their fatigue. But with this report, I do not need to worry it.”

Interviewees felt they already monitored patients’ fatigue closely and, thus, SyMon-SAYS did not change fatigue management, but they still wanted to receive the report.

“...I discussed reports with them occasionally. If we were going to see patients anyway and knew the patient’s status, I did not bother to discuss the report with them.”

Discussions

The literature suggests that symptom management programs in adult cancer patients are feasible, may improve care, enhance patient and provider satisfaction, and lessen symptom burden, while being unlikely to increase provider time and effort. The programs may also increase self-management, which is a desirable goal for children and adolescents who have significant ongoing health care needs related to a chronic illness. However, such programs have not been tested in pediatric oncology. The SyMon-SAYS system is one of the first studies that incorporates an automated computer-assisted symptom monitoring and reporting system for children with cancer, uses both the internet and telephone (to capture economically disadvantaged individuals who do not have internet access), and produces user-friendly symptom reports consisting of graphic displays of scores over time that are presented to both parents and clinicians.

Our study showed that SyMon-SAYS was feasible and acceptable to patients and parents. Overall, they found the SyMon-SAYS was easy to use, were satisfied with SyMon-SAYS, and were willing to complete SyMon-SAYS assessments if they were available for their routine care. However, the SyMon-SAYS did not appear to improve the communication patterns between patients/parents and clinicians, with only 35% of parents reporting that SyMon-SAYS helped them talk to their physicians/nurses. This was not surprising as 71% of parents reported that their doctors or nurses never or seldom discussed the SyMon-SAYS fatigue results with them.

While more than half of clinicians reported that SyMon-SAYS was useful and that they would use it in the future, they did not feel SyMon-SAYS helped with their treatment planning and did not help them focus on the most important issues to discuss with parents/patients. Many of them commented that they monitored patients closely regardless of the availability of SyMon-SAYS; however, they also felt the report was helpful in allowing comparisons of fatigue scores over time. Given the high reputation of Lurie Children’s Hospital, it was not completely surprising that clinicians monitored their patients closely and thus did not feel the SyMon-SAYS improved their communication with patients/families; yet their positive comments about reports themselves are encouraging. The next steps are to test whether the SyMon-SAYS system can be

implemented in other pediatric oncology clinics that are not associated with academic institutions or comprehensive cancer centers, expand the list of symptoms being monitored, and further exploring how symptom reports can be designed to be helpful to patients, families, and clinicians of these clinics.

Conclusions

SyMon-SAYS is feasible and acceptable to patients and parents. Future efforts should focus on better integrating SyMon-SAYS into the clinical workflow to increase clinicians' willingness to include the SyMon-SAYS report into the communication with parents/families.

Significance

This was one of the first studies creating an automated computer-assisted symptom monitoring and reporting system for children with cancer, which has several unique features and could significantly contribute to fatigue management. First, SyMon-SAYS uses both the telephone and internet, media with which children are familiar and comfortable. Although the internet has been integrated into daily life for most children and adolescents, not every family can access it at home. Thus, providing the option to use telephones or internet allows for monitoring on a frequent basis to capture problematic symptoms occurring between scheduled clinical visits. Second, SyMon-SAYS produces user-friendly symptom reports consisting of graphic displays of scores over time that are presented to both parents and clinicians. Patients and their parents were able to compare patients' current fatigue to a previous state, enabling prompt medical attention and self-management.

Implications

This study provided evidence that a real-time symptom monitoring and reporting system was feasible. Lessons learned from the current study will lead to the next generation of the SyMon-SAYS system, which can be used for both on-treatment patients as well as long-term cancer survivors who are seen by the community healthcare providers.

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List of Publications and Products

We are currently preparing a formal manuscript to be submitted for publication consideration. The results from this study have been presented in several national and international conferences:

Presentations

1. 15th International Symposium on Pediatric Neuro-Oncology, June 24-27, 2012, Toronto, Canada
2. 34th Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine, March 20-23, 2013, San Francisco.
3. The Symptom Monitoring And Systematic Assessment In Young Survivors (SyMon-SAYS) For Pediatric Oncology Clinics. Paper presented at the 45th Congress of the International Society of Paediatric Oncology, September 25-28, Hong-Kong, 2013.